

REMARKS

In reply to the Office Action dated November 1, 2005, reconsideration is respectfully requested in view of the above amendments and the following remarks. As noted by the Examiner, Claim 6 is currently pending and under consideration in the application.

Claim Objections

Claim 6 was objected to as missing an article before the word "nucleic." This typographical error has been corrected by the above amendment via the insertion of "the" before "nucleic," as suggested by the Examiner. Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. § 112

Claim 6 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. More particularly, the Examiner asserts that it is unclear what a "predetermined cut-off value" is or how it is determined.

Applicants respectfully traverse. As an initial matter, Applicants submit that a skilled artisan would understand the instant specification to establish, as noted by the Examiner, that a polypeptide encoded by SEQ ID NO: 10,582 is useful as a diagnostic marker for lymphomas. In view of this disclosure by Applicants, it is respectfully submitted that the skilled artisan could readily determine an appropriate cut-off value for practicing the claimed methods, particularly in light of the instant specification and further in view of what is well known and understood in the diagnostic arts. A predetermined cut-off value, for example, can be determined from any of a number of control sample types and this would be readily recognized by the skilled artisan. Indeed, the specification as filed provides illustrative guidance in the context of the claimed invention for determining a cut-off value and using the cut-off value in the claimed diagnostic methods. For example, at page 125, lines 10-13, the specification as filed describes that a polypeptide of the invention is generally present at a level that is at least three-fold higher in samples obtained from a cancer patient relative to a sample obtained from a normal patient that does not have cancer. Thus, as would be understood, a predetermined cut-off value can be determined by analyzing the expression of the claimed sequence in one or more

normal control samples (e.g., from patients not afflicted with cancer), and determine an appropriate predetermined cut-off value for use in the claimed methods. In addition, at the paragraph bridging pages 127 and 128, the specification provides further illustrative guidance that predetermined cut-off values may be determined from control samples derived from patients without cancer. Thus, Applicants submit that the present disclosure provides more than adequate guidance regarding the determination and selection of a cut-off value and, thus, provides reasonable clarity under 35 U.S.C. § 112, second paragraph, for the claimed method. Indeed, the situation is analogous to claims directed to a therapeutically effective amount of a compound, where courts have recognized that determining effective dosage for a pharmaceutical agent against a particular disease is well within the ordinary skill in the art. *In re Bundy*, 209 U.S.P.Q. 48 (C.C.P.A. 1981). Applicants respectfully request reconsideration of this rejection.

Claim 6 also stands rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification, while being enabling for a method for detecting the presence of lymphomas in a patient, does not reasonably provide enablement for methods for detecting the presence of every type of cancer. Without acquiescing to the stated grounds for rejection, and without prejudice to prosecution of such subject matter in a related application, Applicants have amended claim 6 to specify that the cancer being detected by the claimed methods is a lymphoma. Reconsideration is respectfully requested.


All of the claims are believed to be in condition for allowance. The Examiner is invited to contact the undersigned with any questions regarding this matter.

Application No. 10/057,475
Reply to Office Action dated November 1, 2005

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



Jeffrey Hundley, Ph.D., Patent Agent
Registration No. 42,676

JEH:mcs

Enclosure:
Postcard

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

752836_1.DOC